

# Identifying, Disposing, and Reporting COVID-19 Vaccine Wastage

This page provides information to help awardees and immunization managers identify, handle, dispose of, and report waste in **COVID-19 vaccination programs**. However, this waste management guidance should not be used for non-COVID-19 vaccines, which are covered under other Centers for Disease Control and Prevention (CDC) vaccination programs.

As more Americans get vaccinated, COVID-19 cases, outbreaks, hospitalizations, and deaths would be expected to decline significantly. In the efforts to expand access to COVID-19 vaccines, providers should take every opportunity to **vaccinate all eligible persons** with a primary series or booster dose.

However, as the rate of vaccine administration slows, the likelihood of leaving unused doses in a vial may increase, even when providers continue to follow best practices to use every dose possible.

CDC develops policies and procedures to help jurisdictions and planners handle COVID-19 vaccine waste. Jurisdictions should review and update existing vaccination plans to implement these vaccine wastage practices. Due to existing regulatory requirements, jurisdictions may need to develop standard operating procedures (SOPs) for medical waste disposal **in** accordance with state law and local practice.

### **Identifying Waste**

Even when every effort is made to reduce the volume of wastage in a vaccination program, sometimes it is necessary to identify doses as "waste" to ensure patient safety and vaccine effectiveness. For example, when there is insufficient volume in the vial for use or when the vaccine dose is spoiled or expired, the dose might be identified as wasted.

Additional instances when vaccine may be identified as waste include:

#### A temperature monitoring device indicates that the vials are out of temperature range.

COVID-19 vaccine temperatures must be monitored using a digital data logger (DDL) with vaccine storage units on site and with shipping containers during transport. **Any time a temperature monitoring device indicates that the vials are out of temperature range, this is a temperature excursion** and the vaccine may need to be identified as waste.

This applies to temperature monitoring devices included in initial vaccine shipping containers (e.g., Pfizer-BioNTech requires the Controlant temperature monitoring device in its shipping containers).

If a temperature excursion occurs, contact the manufacturer to determine if the vaccine can still be used. If the vaccine is determined to be non-viable, it must be declared as waste and destroyed according to local regulations.

Avoid temperature excursions by ensuring that appropriate temperature monitoring devices and storage units are available at on-site and off-site locations and during transport.

Each COVID-19 vaccine product has different limits on the time the vial remains viable once it is removed from the freezer or refrigerator and once a vial is punctured.

If these times are exceeded, vials must be identified as "waste" and destroyed in accordance with local regulations.

Each vaccine vial is labeled with a maximum number of doses.

This is dependent on the type of needle and syringe used to extract the doses. If low dead-volume needles and syringes are not available, the vial will contain fewer doses than identified on the label. In this case, the remaining unused dose will be identified as waste. Remaining vaccine from multiple vials cannot be combined to make a single dose.

#### COVID-19 vaccines contain no preservative and have a limited shelf life.

Any vial of vaccine that exceeds the shelf life indicated by the manufacturer should be disposed of as regulated medical waste in consultation with the manufacturer. Because COVID-19 vaccine expiration dates may change, always check with the manufacturer to determine expiration dates before disposing of the product.

#### Compromised COVID-19 Vaccine Vials

Vials of COVID-19 vaccines (Pfizer-BioNTech, Moderna, Johnson & Johnson/Janssen) are monitored during shipment to ensure the temperature remains within a prescribed range.

Jurisdictions should ensure that providers know they must:

- · Open vaccine packages immediately,
- Check the temperature monitor device,
- Inspect the vaccine,
- Compare the vaccine received with the vaccine product on the packing list, and
- Store vaccine at the appropriate temperature

If the provider believes the vaccine shipment is compromised, temperature monitors are out of range, or monitors have not been activated, providers should place the vaccine in the proper vaccine storage unit at the recommended temperature and mark it as "DO NOT USE" until they receive additional guidance. If there are concerns about temperature excursions during shipment, providers and/or awardee staff should also immediately contact the manufacturer (for the Pfizer-BioNTech vaccine) or McKesson (for centrally distributed Moderna and Johnson & Johnson/Janssen vaccines) to report the excursion.

Providers are also required to monitor temperatures of vaccines stored on site. If there is a temperature excursion while vaccine is stored on site, the vaccine should be separated from viable vaccine, maintained at the proper vaccine storage temperature, and marked as "DO NOT USE." The provider or awardee staff should then contact the manufacturer for guidance about vaccine viability following the guidance in CDC's Vaccine Storage and Handling Toolkit.

If guidance from CDC or the manufacturer indicates the vaccine cannot be used, providers should remove the vials from storage and dispose of them in accordance with state law and local practice to avoid unintentional administration. Report the discarded vaccine as waste as directed in the "Reporting COVID-19 Vaccine Wastage" section.

#### Disposing of COVID-19 Vaccine Waste

The COVID-19 Vaccination Provider Agreement states that providers should dispose of COVID-19 vaccine waste in accordance with local regulations and processes currently being used to dispose of regulated medical waste.

# Reporting COVID-19 Vaccine Wastage

The COVID-19 Vaccination Program Agreement requires providers to report wastage information in the Vaccine Tracking System (VTrckS). To document wasted COVID-19 vaccines:

- Use the VTrckS ExIS (External Information System) Interface for Wastage\* to report vaccine that cannot be administered because it is spoiled/wasted or expired.
- If the CDC-recommended number of doses cannot be extracted from a vial, it must be recorded as waste. Use the same VTrckS ExIS Interface for Wastage\* and select "other" as the option for wastage code. (See Wastage Identification Table for recommended doses per vial.)
- Jurisdictions should follow their routine processes for submitting wastage information to VTrckS by either by uploading a wastage file using the ExIS interface in VTrckS or by direct entry into VTrckS.

- Federal agencies and pharmacies can use Vaccine Provider Ordering Portal (VPoP) \( \text{VPoP} \) to generate wastage files to upload into VTrckS.
- Required fields for submitting wastage information into VTrckS include:
  - a. Provider PIN
  - b. National Drug Code (NDC)
  - c. number of doses wasted
  - d. wastage reason (this is required; use one of the wastage codes provided in VTrckS)

\*Details about reporting vaccine wastage are available in the VTrckS Training Library (jurisdictions) and at the VTrckS Materials for Commercial and Federal Partners link in SAMS (federal agencies/pharmacy chains).

# Strategies and Tips to Reduce COVID-19 Vaccine Waste

Waste is expected in any vaccination program. Wastage reporting helps CDC better understand how much inventory is in the field and where the greatest needs for inventory exist to minimize the potential waste of vaccine. Throughout each phase of the CDC COVID-19 Vaccination Program, jurisdictions, providers and partners have employed strategies to maximize opportunities to vaccinate eligible persons while minimizing waste.

Some of these strategies include:

- Completing comprehensive plans and SOPs for administration of COVID-19 vaccine.
- Understanding state laws and regulations for the disposal of medical waste.
- Implementing measures to reduce waste in COVID-19 vaccine storage, transport, handling, and administration in accordance with the CDC and manufacturer's guidance.

Some tips that can assist providers in ensuring COVID-19 vaccine doses are not wasted:

- If there are a substantial number of expiring vials, reach out to the jurisdiction partners and across vaccination channels to discuss redistribution of vaccine to areas of need.
- Work with the jurisdiction in advance to determine thresholds for the number of vials in danger of being wasted that would trigger a call for guidance.
- Make every effort to coordinate the number of vials needed with the anticipated number of patients when preparing for daily clinics to help reduce over-thawing of vaccine.

#### Once punctured, multidose vials must be used within:

- 12 hours
  - Pfizer (<4 years of age; maroon cap)</li>
  - Pfizer (5-11 years of age; orange cap)
  - Moderna
- 6 hours
  - Pfizer (12+ years of age; purple cap)
  - Johnson & Johnson's Janssen (must be between 2°C and 8°C)
  - Novavax
- 2 hours
  - Johnson & Johnson's Janssen (at room temperature)

# Vaccine Wastage Best Practices

CDC and agency partners are doing everything possible to minimize the amount of vaccine that goes unused. Vaccine wastage may increase as the vaccine rollout continues because:

- more providers, including smaller provider sites, are now receiving vaccine
- vaccine continues to be available only as multi-dose vials
- · vials must often be punctured without using the full number of doses printed on the label

To ensure providers do not miss an opportunity to vaccinate every eligible person, CDC recommends:

• Providers follow both clinical and inventory management best practices for vaccination to maximize vaccination and

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- Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose.
  - Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice.
  - Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events for primary or booster doses.

CDC remains committed to helping jurisdictions and sites manage inventory and creating additional strategies to minimize vaccine wastage, including increased use of walk-in clinics.

#### Vaccine Manufacturer Contact Information

Pfizer Customer Service: (800) 666-7248 or cvgovernment@pfizer.com

Moderna Customer Service: 1-866-MOD-ERNA or 1-866-663-3762

Janssen Customer Service: 1-800-565-4008 or JSCCOVIDTEMPEXCURSION@its.jnj.com

McKesson Customer Service: 1-833-272-6634 or SNSSupport@McKesson.com

Novavax Customer Service: 1-800-NOVAVAX or 1-844-668-2829

# Additional Resources CDC COVID-19 Vaccination Program Playbook COVID-19 Vaccine Storage and Handling Toolkit Recommendations and Guidelines on Proper Vaccine Storage and Handling For Immunization Managers: Awardee Immunization Websites

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